

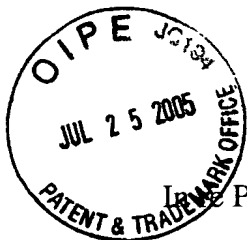


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TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	10/848,922	
		Filing Date	May 18, 2004	
		First Named Inventor	WEISBURG <i>et al.</i>	
		Group Art Unit / Conf. No.	1645 / 5696	
		Examiner Name	Navarro, A.	
Total Number of Pages in This Submission	09	Attorney Docket No.	GP142-02.UT	
ENCLOSURES (check all that apply)				
<input checked="" type="checkbox"/> Information Disclosure Statement Under 37 CFR § 1.97(b) & (c) <u>2</u> pgs.		<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <input checked="" type="checkbox"/> Return/Prepaid Postcard		
<input checked="" type="checkbox"/> PTO/SB/08a & b - 3 pgs. in duplicate <u>6</u> pgs.				
<input checked="" type="checkbox"/> Twenty (20) References		Remarks: No fee is believed due with the filing of the Information Disclosure Statement. If Applicants are in error and a fee is due, please debit Deposit Account No. 07-0835, in the name of Gen-Probe Incorporated, the appropriate amount.		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT				
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Date	July 22, 2005			
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor Patent Application of:)	Group Art Unit: 1645
)	
WEISBURG <i>et al.</i>)	Examiner: Navarro, A.
)	
Serial No. 10/848,922)	Confirmation No. 5696
)	
Filed: May 18, 2004)	Atty. Docket No. GP142-02.UT
)	
For: COMPOSITIONS, METHODS)	
AND KITS FOR DETERMINING)	
THE PRESENCE OF)	
TRICHOMONAS VAGINALIS)	
IN A TEST SAMPLE)	

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97(b) & (c)**

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Applicants bring to the Examiner's attention the references listed on the enclosed PTO/SB/08 forms (two copies each) for consideration in connection with the examination of the above-identified application. In accordance with 37 C.F.R. § 1.98, a copy of each reference listed on the PTO/SB/08 forms, other than the listed U.S. patents, is enclosed herewith.

This Information Disclosure Statement is being submitted under 37 C.F.R. § 1.97(b) before the mailing date of a first Office action on the merits. If Applicants are mistaken, and a first Office action on the merits was mailed on or before the certified date of mailing indicated below, then Applicants request that this Information Disclosure Statement be treated as a submission under 37 C.F.R. § 1.97(c) and that the fee due under 37 C.F.R. § 1.17(p) be charged to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

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Serial No. 10/848,922
Atty. Docket No. GP142-02.UT

Applicants respectfully request that the Examiner indicate consideration of each cited reference by returning a copy of the enclosed form PTO/SB/08 with the Examiner's initials or other appropriate marks.

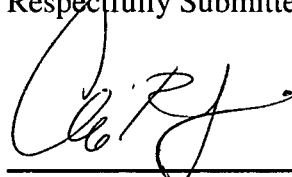
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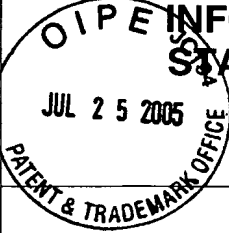
By:



Charles B. Cappellari
Registration No. 40,937
Attorney for Applicants

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				Complete if Known	
				Application Number	10/848,922
				Filing Date	5/18/2004
				First Named Inventor	WEISBURG <i>et al.</i>
				Art Unit / Conf. No.	1645 / 5696
(Use as many sheets as necessary)				Examiner Name	Navarro, A.
Sheet	1	of	3	Attorney Docket Number	GP142-02.UT

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-5,185,439 A	02-09-1993	Arnold, Jr. <i>et al.</i>	
		US-5,399,491 A	03-21-1995	Kacian <i>et al.</i>	
		US-5,654,418 A	08-05-1997	Sheiness <i>et al.</i>	
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		US-6,130,038 A	10-10-2000	Becker <i>et al.</i>	
		US-6,361,945 B1	03-26-2002	Becker <i>et al.</i>	
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FOREIGN PATENT DOCUMENTS						
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		WO89/04876 A1	06-01-1989	ML Technology Ventures, L.P.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/848,922
				Filing Date	5/18/2004
				First Named Inventor	WEISBURG <i>et al.</i>
				Art Unit	1645 / 5696
(Use as many sheets as necessary)				Examiner Name	Navarro, A.
Sheet	2	of	3	Attorney Docket Number	GP142-02.UT
NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
		BROWN <i>et al.</i> , "Evaluation of the Affirm Ambient Temperature Transport System for the Detection and Identification of <i>Trichomonas vaginalis</i> , <i>Gardnerella vaginalis</i> , and <i>Candida</i> Species from Vaginal Fluid Specimens," J. Clin. Microbiol., Sept. 2001, 39(9):3197-3199, ASM, USA			
		COTCH <i>et al.</i> , "Trichomonas vaginalis Associated With Low Birth Weight and Preterm Delivery," Sex. Transm. Dis., July 1997, 24(6):353-360, Lippincott, USA			
		CU-UVIN <i>et al.</i> , "Prevalence, Incidence, and Persistence or Recurrence of Trichomoniasis among Human Immunodeficiency Virus (HIV)-Positive Women and among HIV-Negative Women at High Risk for HIV Infection," Clin. Infect. Dis., May 2002, 34:1406-1411, The University of Chicago Press, USA			
		GARCIA, "Protozoa from Other Body Sites," Diagnostic Medical Parasitology, 2001, 4 th ed., pp. 120-131, ASM Press, USA			
		Gen-Bank Accession No. U17510, "Trichomonas vaginalis 16S-like rRNA gene," Nov. 30, 1995			
		GUNDERSON <i>et al.</i> , "Phylogeny of Trichomonads Inferred from Small-Subunit rRNA Sequences," J. Euk. Microbiol., Jul.-Aug. 1995, 42(4):411-415, Society of Protozoologists, USA			
		JORDAN <i>et al.</i> , "TaqMan-Based Detection of <i>Trichomonas vaginalis</i> DNA from Female Genital Specimens," J. Clin. Microbiol., Nov. 2001, 39(11):3819-3822, ASM, USA			
		KAYDOS <i>et al.</i> , "Development and Validation of a PCR-Based Enzyme-Linked Immunosorbent Assay with Urine for Use in Clinical Research Settings to Detect <i>Trichomonas vaginalis</i> in Women," J. Clin. Microbiol., Jan. 2002, 40(1):89-95, ASM, USA			
		KIKUTA <i>et al.</i> , "Specific and sensitive detection of <i>Trichomonas tenax</i> by the polymerase chain reaction," Lett. Appl. Microbiol., 24:193-197, The Society for Applied Bacteriology, Blackwell Publishing, UK			
		KRIEGER <i>et al.</i> , "Diagnosis of Trichomoniasis – Comparison of Conventional Wet-Mount Examination With Cytologic Studies, Cultures, and Monoclonal Antibody Staining of Direct Specimens," JAMA, Feb. 1988, 259(8):1223-1227, American Medical Association, USA			
		LEBER <i>et al.</i> , "Intestinal and Urogenital Amebae, Flagellates, and Ciliates," Manual of Clinical Microbiology, 7 th ed., 1999, pp. 1391-1405, ASM Press, USA			

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
		MAYATA <i>et al.</i> , "18S Ribosomal DNA-Based PCR for Diagnosis of <i>Trichomonas vaginalis</i> ," J. Clin. Microbiol., July 2000, 38(7):2683-2687, ASM, USA			
		NICCOLAI <i>et al.</i> , "Incidence and Predictors of Reinfection with <i>Trichomonas vaginalis</i> in HIV-infected Women," Sex. Transm. Dis., May 2000, 27(5):284-288, Lippincott, USA			
		REIN, " <i>Trichomonas vaginalis</i> ," Principles and Practice of Infectious Diseases, 5 th ed., 2000, pp.2894-2898, Churchill Livingstone, USA			
		SORVILLO <i>et al.</i> , " <i>Trichomonas vaginalis</i> , HIV, and African-Americans," Emerg. Infect. Dis., Nov.-Dec. 2001, 7(6):927-932, CDC, USA			
		SORVILLO <i>et al.</i> , "Risk Factors for Trichomoniasis Among Women With Human Immunodeficiency Virus (HIV) Infection at a Public Clinic in Los Angeles County, California: Implications for HIV Prevention," Am. J. Trop. Med. Hyg., 1998, 58(4):495-500, The American Society of Tropical Medicine and Hygiene, USA			
		TER KUILE <i>et al.</i> , "Influence of growth conditions on RNA levels in relation to activity of core metabolic enzymes in the parasitic protists <i>Trypanosoma brucei</i> and <i>Trichomonas vaginalis</i> ," Microbiol., 1999, 145:755-765, SGM, UK			
		VAN DER SCHEE <i>et al.</i> , "Improved Diagnosis of <i>Trichomonas vaginalis</i> Infection by PCR Using Vaginal Swabs and Urine Specimens Compared to Diagnosis by Wet Mount Microscopy, Culture, and Fluorescent Staining," J. Clin. Microbiol., Dec. 1999, 37(12):4127-4130, ASM, USA			
		WENDEL <i>et al.</i> , " <i>Trichomonas vaginalis</i> Polymerase Chain Reaction Compared with Standard Diagnostic and Therapeutic Protocols for Detection and Treatment of Vaginal Trichomoniasis," Clin. Infect. Dis., Sept. 2002, 35:576-580, The University of Chicago Press, USA			

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